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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

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Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

Claims 8, 11-13, 15, 16, 18-34, 38 and 39 are pending in this application.

#### ***Action Summary***

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The rejection of claims 8, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38 under 35 U.S.C. 103(a) over SmithKline Beecham Co. in view of Katz et al. is hereby withdrawn with respect to applicants' arguments.

#### ***Response to Arguments***

3. Applicant's arguments with respect to claims 8, 11-13, 15, 16, 18, 19, 22-26, 29, 30, 32-34 and 38 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps requiring application to the skin or topical application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8, 11-13, 15, 16, 18-33, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over SmithKline Beecham Co. (WO 95/06410) in view of Sekine et al. (WO 97/28794 as translated by US 6,054,484) and RxList Monographs (1999).

SmithKline Beecham Co. ('410) discloses the use of angiotension II receptor antagonist as a medicament for the treatment of chronic inflammatory diseases, which can be formulated for transdermal delivery as a patch or membrane, and when formulating the composition topically the composition can contain non-toxic auxiliary substances such as emulsifying agent, polyols, etc. (page 28, lines 2-7 and page 29, lines 14-32). Claim 13, page 41, lines 29-33 teach that the angiotension II receptor antagonist is 1-(cyclohexyloxycarbonyloxy) ethyl-2-ethoxy-1- [(2'-(1H-tetrazol-5-yl) biphenyl-4-yl) methyl]-benzimidazole-7-carboxylate or pharmaceutically acceptable salt. The prior art does not teach the preparation comprising a fatty acid ester or the angiotension II antagonistic activity.

Sekine et al. discloses in Table 14, a cataplasm (see col. 5, lines 25-31 for description) comprising a fatty acid ester (isopropyl myristate at a concentration of 1%), a polyol (propylene glycol at a concentration of 10%) and a nonionic surfactant (coconut fatty acid diethanolamide at a concentration of 2%) (col. 20, lines 1-22). Column 7, lines

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13-18 describe a formulation of a self-adhesive cataplasm by adding a polymer (polybutene) and gelatin.

RxList Monograph discloses information about 1-(cyclohexyloxycarbonyloxy) ethyl-2-ethoxy-1- [(2'-(1H-tetrazol-5-yl) biphenyl-4-yl) methyl]-benzimidazole-7-carboxylate also known as Candesaratan cilexetil.

Sekine et al. teaches the preparations using diclofenac sodium as the active agent. Column 1, lines 53-60 teach that diclofenac sodium has 1.5% solubility in water. RxList Monographs teach that Candesaratan cilexetil is practically insoluble in water. Therefore, when formulating a compound that is poorly soluble in water such as Candesaratan cilexetil into a transdermal delivery system, one of ordinary skill in the art could look to Sekine et al. as a method of formulating a compound that has poor solubility in water into a transdermal delivery device with the addition of compounds that can aid in penetration i.e. polyols, surfactants and fatty acids.

With respect to the angiotension II antagonistic activity, absent a clear showing of criticality, the determination of angiotension II antagonistic activity is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

### ***Conclusion***

6. Claims 8, 11-13, 15, 16, 18-34, 38 and 39 are rejected.

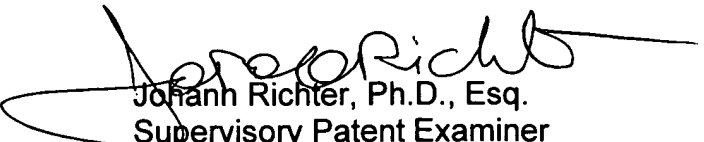
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

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Konata M. George  
Patent Examiner  
Technology Center 1600

  
Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600